

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

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| MARION GUYNN, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | Cause No. 3:14-cv-1784 RLM-MGG |
| |) | |
| BIOMET, INC., <i>et al.</i> , |) | |
| |) | |
| Defendants. |) | |

OPINION AND ORDER

Marion Guynn sued Biomet for damages in connection with the alleged failure of his Biomet M2a-38 hip implant. Biomet moved for summary judgment, arguing that his claims are time-barred based on (1) a proposed date on which all plaintiffs were on constructive notice of potential claims and (2) facts specific to Mr. Guynn. I disagree with both of Biomet's arguments, and deny Biomet's summary judgment motion.

I. STANDARD OF REVIEW

Summary judgment is appropriate when the pleadings, discovery materials, disclosures, and affidavits demonstrate no genuine issue of material fact, such that the movant is entitled to judgment as a matter of law. Protective Life Ins. Co. v. Hansen, 632 F.3d 388, 391-92 (7th Cir. 2011). I must construe the evidence and all inferences that reasonably can be drawn from the evidence in the light most favorable to Mr. Guynn, as the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). As the moving party, Biomet bears

the burden of informing me of the basis for its motion, together with evidence demonstrating the absence of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If Biomet meets that burden, Mr. Guynn can't rest upon the allegations in the pleadings, but must "point to evidence that can be put in admissible form at trial, and that, if believed by the fact-finder, could support judgment in his favor." Marr v. Bank of Am., N.A., 662 F.3d 963, 966 (7th Cir. 2011); *see also* Hastings Mut. Ins. Co. v. LaFollette, No. 1:07-cv-1085, 2009 WL 348769, at *2 (S.D. Ind. Feb. 6, 2009) ("It is not the duty of the court to scour the record in search of evidence to defeat a motion for summary judgment; rather, the nonmoving party bears the responsibility of identifying the evidence upon which he relies."); Hammel v. Eau Galle Cheese Factory, 407 F.3d 852, 859 (7th Cir. 2005) (summary judgment is "not a dress rehearsal or practice run; it is the put up or shut up moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of events").

II. THE PROPOSED BAR DATE

First, Biomet asks me to establish a bar date applicable to all plaintiffs. Biomet argues that enough information was publicly available to put any reasonable plaintiff on notice by February 10, 2011 that her injury might be connected to Biomet's M2a metal-on-metal hip implant. As Biomet sees it, if a plaintiff was injured on or before February 10, 2011, the statute of limitations

would begin to run then. If the plaintiff was injured after February 10, 2011, the statute of limitations would begin to run on the date of injury.

The discovery rule postpones the accrual of a cause of action until the plaintiff knew, or through exercise of reasonable diligence should have known, that she was injured. *See, e.g.*, Fla. Stat. § 95.031(2)(b); 735 Ill. Comp. Stat. 5/13-213(d); N.C. Gen. Stat. § 1-52(16); Wash. Rev. Code § 7.72.060(3); Martin v. Arthur, 3 S.W.3d 684, 690 (Ark. 1999); In re Med. Review Panel of Howard, 573 So. 2d 472, 474 (La. 1991); Moreno v. Sterling Drug, Inc., 787 S.W.2d 348, 351 (Tex. 1990).

Biomet contends that this publicly available information put a reasonable plaintiff on notice of a potential claim by the proposed bar date: the device's Instructions for Use, articles in medical journals, press reports, and the Food and Drug Administration's websites. The Instruction for Use for Biomet's metal-on-metal hip implants disclosed that using the device could pose a risk of exposure to metal debris, including osteolysis, metal hypersensitivity, and elevated metal ion levels. Eight 2010 medical journal articles raised concerns about the risks associated with metal-on-metal hip implants, including an editorial in the Journal of Arthroplasty, the official, peer-reviewed journal of the Association of Hip and Knee Surgeons. *See* Ross Crawford et al., *Metal on Metal: Is it Worth the Risk?*, J. ARTHROPLASTY, Sept. 2010, at 1.¹

¹ *See also* Joseph Daniel et al., *Renal Clearance of Cobalt in Relation to the Use of Metal-on-Metal Bearings in Hip Arthroplasty*, 92 J. BONE & JOINT SURGERY 840 (2010); C. Delaunay et al., *Metal-on-Metal Bearings Total Hip Arthroplasty: The Cobalt and Chromium Ions Release Concern*, 96 ORTHOPAEDICS & TRAUMATOLOGY: SURGERY & RESEARCH 894 (2010); Brian M. Devitt et al., *Cobalt Ions Induce Chemokine Secretion in*

Biomet argues that news reports from early 2010 reporting on the risks of metal debris with metal-on-metal hip implants also put plaintiffs on notice of potential claims. *See, e.g.,* Barry Meier, *As Use of Devices Grows, Studies Raise Concerns*, N.Y. TIMES, Mar. 4, 2010.² More news reports followed DePuy's August 2010 recall of two ASR metal-on-metal hip implants. *See, e.g.,* Natasha Singer, *Hip Implants Are Recalled by J. & J. Unit*, N.Y. TIMES, Aug. 27, 2010.³

Last, Biomet contends that the FDA notified the public when it launched two websites discussing potential health risks of metal-on-metal hip implants by February 10, 2011. *See Concerns about Metal-on-Metal Hip Implant Systems*, FOOD & DRUG ADMIN. (last updated Feb. 10, 2011), <https://web.archive.org/web/20110214064145/http://www.fda.gov/MedicalD>

a Variety of Systemic Cell Lines, 81 ACTA ORTHOPAEDICA 756 (2010); Monika Huber et al., *Postmortem Study of Femoral Osteolysis Associated with Metal-on-Metal Articulation in Total Hip Replacement*, 92 J. BONE & JOINT SURGERY 1720 (2010); Takao Imanishi et al., *Serum Metal Ion Levels after Second-Generation Metal-on-Metal Total Hip Arthroplasty*, 130 ARCHIVES ORTHOPAEDIC & TRAUMA SURGERY 1447 (2010); Ajay Malviya et al., *Metal-on-Metal Total Hip Arthroplasty*, 92 J. BONE & JOINT SURGERY 1675 (2010); Michael C. Parry et al., *Thresholds for Indirect DNA Damage Across Cellular Barriers for Orthopaedic Biomaterials*, 31 BIOMATERIALS 4477 (2010).

² *See also* Barry Meier, *When New Hips Go Bad*, N.Y. TIMES, Mar. 4, 2010; Barry Meier, *Alert Follows Withdrawal Of Hip Device*, N.Y. TIMES, Mar. 10, 2010; Harvard Health Letters, *Hip Replacement Candidates Have Several Surgical Options*, SUN-SENTINEL, Mar. 24, 2010; Sue Scheible, *You Don't Have to Be Old to Get a New Knee, Hip or Shoulder*, NEB. CITY NEWS-PRESS, Apr. 5, 2010; Peter Benesh, *Stryker Promotes Hip Technology*, INVESTOR'S BUS. DAILY, Apr. 16, 2010.

³ *See also* Jonathan D. Rockoff & Jon Kamp, *J&J's Latest Recall: Hip-Repair Implants*, WALL ST. J., Aug. 27, 2010; Nora Tooher, *Litigation Mounts over DePuy Hip Replacement Device*, LAWYERS WEEKLY USA, Oct. 4, 2010; Nelson Daranciang, *Woman Sues over Hip Implant Device*, HONOLULU STAR-ADVERTISER, Oct. 27, 2010; Steve Daniels & Silvia Gambardella, *Hip Implant Recalled Amid Concerns About Heart Failure, Dementia*, ABC NEWS, Dec. 1, 2010; Barry Meier, *The Implants Loophole*, N.Y. TIMES, Dec. 17, 2010; Barbara Peters Smith, *The Enemy Within*, SARASOTA HERALD TRIB., Dec. 21, 2010.

evices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal HipImplants/ucm241604.htm; *Information for Patients Who Have Metal-on-Metal Hip Implants*, FOOD & DRUG ADMIN. (last updated Feb. 10, 2011), <https://web.archive.org/web/20110528045143/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal HipImplants/ucm241766.htm>. These websites warned that metal-on-metal hip implants might leave debris that could damage bones and tissue surrounding the implant, and encouraged people to contact their physicians if they experienced any symptoms. Biomet argues that the combined effect of the Instructions for Use, journal articles, press reports, and FDA warnings would have put a reasonable person on notice of the connection between Biomet's device and an injury from exposure to metal and metal debris no later than February 10, 2011.

Three district court decisions in MDL dockets inform Biomet's analysis. In *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, Judge Rufe held that a bar date was appropriate because the cumulative effect of publicity about a prescription drug's relationship to adverse cardiovascular events was sufficient, as a matter of law, to put an individual who had been injured on notice that Avandia could be to blame. No. 07-MD-01871, 2012 WL 3205620, at *4 (E.D. Pa. Aug. 7, 2012). This publicity included:

1. a New England Journal of Medicine study finding that Avandia increased the risk of heart problems by forty-three percent;

2. a joint statement from the American College of Cardiology, the American Diabetes Association, and the American Heart Association expressing concern and advising patients to speak to their physicians;
3. an FDA advisory committee conclusion that Avandia increased heart risk;
4. FDA action requiring that a warning be added to Avandia's label;
5. the drug manufacturer sending letters to healthcare professionals on studies linking Avandia and heart health;
6. the drug manufacturer publishing a "Dear Patient" letter about the risks of heart problems;
7. a wave of media attention following the above, including lead stories on the national nightly news; and
8. numerous lawsuits filed against the drug manufacturer, leading to the formation of the MDL.

Id. at *3. Evidence that Avandia prescriptions dropped by forty-five percent and sales by fifty-four percent as of the proposed bar date showed that these events "were regarded as significant by physicians, patients, and attorneys." *Id.* at *4.

In an MDL docket involving Vioxx, Judge Fallon applied a bar date to multiple plaintiffs based on:

1. a medical study finding that Vioxx triggered a significant increase in abnormal cardiovascular events;
2. media reports linking Vioxx to cardiovascular risks;

3. a new Vioxx label that the manufacturer submitted, the FDA approved, and resulted in substantial press coverage;
4. filing of a class action; and
5. the manufacturer removing Vioxx from the market, triggering “arguably the largest and most-publicized prescription drug withdrawal in this country's history.”

In re Vioxx Prods. Liab. Litig., 522 F. Supp. 2d 799, 803, 808, 814 (E.D. La. 2007). The court held that “[b]oth the national and local media coverage of the withdrawal of Vioxx from the market were sufficient to put the plaintiffs on notice of a potential link between their alleged injuries and the use of Vioxx.” *Id.* at 808.

In the Zyprexa litigation, Judge Weinstein held that a bar date was appropriate when:

1. the FDA announced it would require an additional warning on the drug's label;
2. leading medical associations issued a consensus statement concluding that Zyprexa posed a risk; and
3. the drug manufacturer distributed a “Dear Doctor” letter to physicians nationwide informing them of the label change.

In re Zyprexa Prods. Liab. Litig., 727 F. Supp. 2d 101, 107 (E.D.N.Y. 2010); *see also* Burrell v. Astrazeneca LP, No. CIV.A. 07C01412(SER), 2010 WL 3706584, at *6 (Del. Super. Sept. 20, 2010) (establishing a bar date in litigation regarding Astrazeneca's Seroquel).

I can't say that, as a matter of law, the notice to a reasonable plaintiff of a potential claim against Biomet approached what happened in the Avandia, Vioxx and Zyprexa cases. First, in both the Avandia and Zyprexa cases, the manufacturer published or distributed letters alerting patients or physicians to the risks associated with the product. This would have been the simplest way for Biomet to put all of its customers on notice of a potential claim, and Biomet chose not to do so.

Second, two of the three cases included substantially more press coverage than that surrounding Biomet. For example, in the Vioxx case, Judge Fallon noted that the press coverage was "arguably the largest and most-publicized prescription drug withdrawal in this country's history." In re Vioxx Prods. Liab. Litig., 522 F. Supp. 2d at 803. In addition, the coverage in Vioxx was the result of the company pulling its product from the market. Biomet didn't opt to make such a clear signal to consumers of its product's potential risk.

Third, two of the three cases included statements from leading medical associations highlighting risks associated with the product. Biomet points to no such statements here.

Fourth, Biomet doesn't demonstrate how a reasonable plaintiff would have seen or understood the Instructions for Use that Biomet argues should have put her on notice. They're directed to the operating surgeon, not the patient. While the Instructions for Use caution about "histological reactions involving various sizes of macrophages and fibroblasts," they then backtrack, explaining that "similar changes may occur as a precursor to or during the healing process."

They explain that “[p]articulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid,” which could “result[] in osteolysis.” They explain a report associating articulating surfaces and “increased genotoxicity.” They also add necessary caveats, that the report “did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions . . . might be responsible for the observed data,” cautioning that “an association does not necessarily mean a causal relationship.” Biomet might show how a reasonable surgeon would have been aware of the product’s risks, but doesn’t show how a reasonable plaintiff should have seen or understood the document.

Last, in two of the three cases, either a class action had been filed or an MDL formed, with the consequent publicity and attorney advertising. The Biomet MDL wasn’t formed until well over a year after Biomet’s proposed bar date.

Under even the most liberal construction of the states’ “discovery rules,” Biomet doesn’t show that these materials would’ve had the cumulative effect of putting all plaintiffs on constructive notice of a potential claim by February 10, 2011. Biomet’s knowledge that it possessed by the proposed bar date can’t be attributed to the reasonable plaintiff. Biomet didn’t target information to patients notifying them of the possible risks or demonstrate that reasonable plaintiffs are reading medical journals or the FDA website. Without a torrent of press coverage surrounding a decision to pull the product from the market or to change its label, Biomet hasn’t shown that a reasonable plaintiff would know of a potential claim. I decline Biomet’s request to establish a February 10, 2011, bar date.

III. MR. GUYNN'S BACKGROUND

Marion Guynn received a Biomet M2a-38 implant in Arkansas in April 2004. The next month he returned to the hospital after some mental status changes, and was found to be hypotensive with an elevated white blood count, indicating that he had an infection. He underwent a revision surgery, in which the femoral head of the hip implant was replaced, and he was treated with irrigation and debridement for the infection. In September 2004, to treat another infection, the implant was replaced with a temporary antibiotic spacer. Less than three years later, in August 2007, Mr. Guynn had another revision to treat an infection, and this time the femoral head and acetabular cup were replaced with components made by Zimmer. He had a final revision surgery in October 2007. Mr. Guynn contacted an attorney in response to a television commercial in 2014 and filed suit in August 2014.

IV. CHOICE OF LAW

When a case is filed directly in the MDL transferee court, the court applies the law, including choice-of-law rules, of the state where the case originated. *E.g., In re Watson Fentanyl Patch Prods. Liability Litig.*, 977 F. Supp. 2d 885, 888 (N.D. Ill. 2013). It's "appropriate to treat a foreign direct-filed case as if it had been filed in the state where the plaintiff purchased and was prescribed the subject [product]." *Id.* (internal quotations omitted). The implant was purchased and prescribed in Arkansas, so Arkansas law governs. Under Arkansas law,

statutes of limitations are procedural, and so Arkansas courts apply Arkansas statutes of limitations, Middleton v. Lockhart, 139 S.W.3d 500, 502-503 (Ark. 2003), as will I.

V. DISCUSSION

Under the Arkansas Product Liability Act, “[a]ll product liability actions shall be commenced within three (3) years after the date on which the death, injury, or damage complained of occurs.” Ark. Code Ann. § 16-116-203. This limitations period governs Mr. Guynn’s strict products liability claims and also his claims based on negligence, Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056, 1059 (W.D. Ark. 2009), and breach of warranty, *see* § 16-116-202(5); Follette v. Wal-Mart Stores, Inc., 41 F.3d 1234, 1236 (8th Cir. 1994) (“[T]he three-year statute of limitations found in the Product Liability Act governs a breach-of-warranty suit when damages for personal injury are sought.”); IC Corp. v. Hoover Treated Wood Prods., Inc., 385 S.W.3d 880, 885 (Ark. Ct. App. 2011).⁴ “[I]n product liability cases, the statute of limitations under § 16-116-[2]03 does not commence running until the plaintiff knew or, by the exercise of reasonable

⁴ A “product liability action” “includes *all* actions brought for or on account of personal injury . . . caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product.” § 16-116-202(5) (emphasis added). The court agrees with the Fields court’s analysis that “a ‘product liability action’ is defined not by the substantive legal theory under which the plaintiff proceeds, but rather by the factual scenario that gives rise to the plaintiff’s claim and the injury that results from the conduct of the defendant.” Fields v. Wyeth, Inc., 613 F. Supp. 2d at 1059. On these grounds, the same limitations period applies to Mr. Guynn’s strict products liability, negligence, and breach of warranty claims, even without an express holding of the Arkansas Supreme Court to that effect. *See Comm’r v. Bosch*, 387 U.S. 456, 465 (1967).

diligence, should have discovered the causal connection between the product and the injuries suffered.” Martin v. Arthur, 3 S.W.3d 684, 690 (Ark. 1999).

How much did Mr. Guynn need to know for the limitations period to run? To trigger the limitations period, discovery of the “full extent of the harm is not required; indeed, the manifestation of the nature of the harm done . . . may be slight.” *Id.* It’s enough that the plaintiff has information that creates “more than a mere suspicion” of the cause of the injury, IC Corp. v. Hoover Treated Wood Prods., Inc., 385 S.W.3d at 884, that he had enough to know of “the connection between the product and [] the ‘nature of the harm.’” Robinson v. Mine Safety Appliances Co., 795 F.3d 879, 881 (8th Cir. 2015).

The continual need for revision surgeries to address infections in his hip and to replace components of the hip implant shows there’s no genuine dispute that Mr. Guynn knew or reasonably should have known of “the connection between” the hip implant and his ongoing infections. *Id.* Within three and a half years, Mr. Guynn received the hip implant and had four revision surgeries. Each revision addressed infections in the hip, more than once through replacing components of the implant.

But a reasonable jury could find from these facts that Mr. Guynn, an elderly patient even in 2004 when his implant was removed, had no basis on which to suspect that his implants were causing metallosis. A reasonable jury could find that if anything, after repeated revision surgeries that opened the hip area to the surgeons’ view, Mr. Guynn had reason to believe metallosis wasn’t his problem. A reasonable juror could find that Mr. Guynn didn’t know of any

connection between the implant and his metallosis before 2014. For the same reasons, no summary judgment can be made for Biomet on the breach of warranty claim, which is governed by a three-year statute of limitations. Ark. Code Ann. § 16-116-102(5).

VI. CONCLUSION

Based on the foregoing, the court DENIES Biomet's motion for summary judgment [Doc. No. 118].

SO ORDERED.

ENTERED: March 26, 2017

/s/ Robert L. Miller, Jr.
Judge
United States District Court